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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,461	12/15/2003	Jonathan Alexander Terrett	2543-1-034	4511

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/736,461	TERRETT, JONATHAN ALEXANDER	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-12,14-16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/07/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XI (claims 13 and 17) in the reply filed on October 23, 2006 is acknowledged. The traversal is on the ground(s) that Group III (claims 2, 4, 11, 12, 14-16 and 18), drawn to an antibody and a medicament are fundamentally related to the elected Group and a search and examination of the entire application and at the least the two aforementioned Groups can be make without serious burden, see page 4 of the Remarks. This is not found persuasive because a product and a method of using a product are patentably distinct inventions as set forth in the Requirement mailed September 28, 2006. Furthermore, the antibody of Group III can be used in several processes and not just the examined Group as noted in the bridging paragraph of pages 4 and 5 of the Requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-18 are pending.

Claims 1-12, 14-16 and 18, drawn to non-elected inventions are withdrawn from examination.

Claims 13 and 17 are examined on the merits.

Priority

3. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on June 14, 2002. It is noted, however, that applicant has not filed a certified copy of the United Kingdom 011644.8 (filed June 15, 2001) application as required by 35 U.S.C. 119(b). Consequently, the priority date afforded to the claims is the date of the PCT/GB02/02779 filed June 14, 2002.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 3, section 0009 for example. Applicant is required to review the entire specification and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 1 as a DTD polypeptide and the antibody that is specific for the DTD protein defined as SEQ ID NO: 1.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants broadly claim a method of prevention and treatment comprising

administering an antibody, which is capable of binding at least one DTD polypeptide. However, Applicants are not entitled, nor is the specification enabled for the use of all DTD proteins and antibodies specific for said an undefined and uncharacterized DTD protein. Applicant is only in possession of one species of DTD, which is SEQ ID NO: 1, see page 3 of the specification, section 0009. Applicants are not permitted to claim all DTD proteins and antibodies that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue. There is no disclosure, beyond the mention of SEQ ID NO: 1 as a DTD protein made in the specification. And as Applicants' claims are written the recitation "DTD polypeptide" could encompass variants, mutants and proteins from not only humans, but other animals. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Applicants can obviate the instant rejection my amending the claims to reflect that the DTD protein of the claims reads specifically on SEQ ID NO: 1 and the corresponding antibody binds specifically to said sequence.

7. Claims 13 and 17 are is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating cancer comprising

administering an antibody capable of binding to at least one DTD polypeptide identified as SEQ ID NO: 1, does not reasonably provide enablement for a method of preventing a cancer with at least one DTD polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants' specification does not establish a method for preventing cancer using the undefined and uncharacterized DTD polypeptides. Applciants do provide four examples on pages 27-29, however none exemplify preventing any disease. The methodology listed in the specification is not commensurate in scope with claims, particularly the method of inhibiting tumor growth in a host predisposed to having a tumor.

There is no guidance in the specification as to how to determine and select a population of individuals, which may or may not eventually have cancer. Preventing a disease is just as complex a process. It is not clear what parameters one skilled in the art would use in order to identify a population of subjects in which cancer could be prevented. It is also not clear what symptoms one of skill in the art would need to identify before possibly treating a patient. While it is art known that clinicians are capable of implementing both screening and surveillance and the type of screening test used and the intervals at which it is performed are based on risk stratification, which also serves as the basis for selecting potential candidates for possible prevention. However, like most screening procedures determining whether a population will eventually be struck with a disease is not fool proof. There is insufficient evidence

provided enabling one of ordinary skill in the art to determine susceptible cancer candidates within a population. The specification provides neither guidance on nor exemplification of identifying a population of people who may eventually have a tumor. Furthermore, if such a group was identified there is insufficient evidence provided that the tumor growth would be inhibited with the administration of a DTD polypeptide.

There would also need to be some valid amount of direction or guidance, as well as presence or absence of working examples presented in the specification that would enable one skilled in the art to perform the method as presented in the recited claims. It appears that undue experimentation would be required of one skilled in the art to practice the instant claimed invention using the teachings of the specification. See Ex parte Forman, 230 USPQ 546 BPAI, 1986.]

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The acronym, DTD is not defined within claim 13. The acronym can represent D-aminoacyl-tRNA deacylase, diastrophic dysplasia or DL-threo-dihydrosphingosine. Applicants should note the proper term followed by the acronym within parentheses.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0108963 A1 (filed July 25, 2002). Publication 2003/0108963 discloses amino acid sequence 369, which shares 99.9% sequence homology with Applicants' SEQ ID NO: 1, which is identified as a DTD polypeptide, see attached database sheet. Antibodies directed against amino acid sequence 369 may be used as therapeutic agents in treating cancer, see section 0193 beginning on page 31 and section 0261 bridging pages 40 and 41.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2003/0108963 A1 (filed July 25, 2002), and in

further view of US Patent Application Publication 2003/0108963 A1 (filed July 25, 2002) and Marin et al. (Br. J. Cancer 76(7): 923-9, 1997). The teachings of US Patent Application Publication 2003/0108963 A1 (filed July 25, 2002) have been presented in the 102(e) rejection. The patent application does not teach the human disease is breast cancer.

However, Marin teaches the DTD enzyme is associated with breast tumors. In light of the lack of the meaning of the DTD acronym and giving the claims the broadest reasonable interpretation, DTD is noted as DT-diaphorase and the instant rejection is applicable to the claims. It would have been *prima facie* obvious at the time of the claimed invention to implement the teachings of Marin, recognizing the art known association between DTD and breast cancer to treat breast cancer with the antibodies of the patent application publication. It would have been *prima facie* obvious at the time of the claimed invention to treat breast cancer given DTD is recognized as a breast cancer marker. One of ordinary skill in the art would have been motivated to combine the teachings of all documents since the sequence homology between the target amino acid sequence is the same and they both teach treating subjects with the same antibodies.

12. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,812,339 (effective filing date October 20, 2000) and in further view of US Patent Application Publication 2003/0108963 A1 (filed July 25, 2002) and Marin et al. (Br. J. Cancer 76(7): 923-9, 1997). U.S. Patent number 6,812,339 teaches amino

acid sequence 10387 which shares 99.9% sequence homology with Applicants' SEQ ID NO: 1, which is identified as a DTD polypeptide, see attached database sheet. Antibodies directed against amino acid sequences 10387 are recognized as modulators, see column 36, line 59-column 37, line 2. These modulators can be administered to treat human disease, see column 35, columns 58-65. The patent does not teach the human disease is breast cancer.

However, the patent application publication teaches implementing an antibody against the same target sequence for the treatment of cancer and Marin teaches the DTD enzyme is associated with breast tumors. In light of the lack of the meaning of the DTD acronym and giving the claims the broadest reasonable interpretation, DTD is noted as DT-diaphorase and the instant rejection is applicable to the claims. It would have been *prima facie* obvious at the time of the claimed invention to implement the teachings of the patent application, treating and preventing cancer in the method of administering modulators to treat human disease. And it would have been *prima facie* obvious at the time of the claimed invention to treat breast cancer given DTD is recognized as a breast cancer marker. One of ordinary skill in the art would have been motivated to combine the teachings of all documents since the sequence homology between the target amino acid sequence is the same and they both teach treating subjects with the essentially the same antibodies.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
05 January 2006